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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/431,519	11/01/1999	SHIH CHUNG	AH0948Q	8808

7590 06/14/2006

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PATENT DEPT K-6-1 1990  
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EXAMINER

LEVY, NEIL S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/431,519	CHUNG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	NEIL LEVY	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 43-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 43-72 are now the only claims in this file.

#### ***Claim Rejections - 35 USC § 112***

Claims 43-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention

However, applicants claims are to a composition, leading one to believe, for example if Zerranol is THE immediate release formulation, a coating of 100% zeranol on a dosage form, pellet or tablet, of zeranol + polymeric controlled release formulation. This is not the instant invention, instead, it is presented as Ralgro pellets constituting the immediate release formulation and an unclaimed # of discrete particles, tablets, as a controlled release formulation.

Upon review of the data in the case, Ralgro, the immediate release form is superior to the controlled release forms, EVEN THOUGH ONLY 72 mg of Ralgro was administered, compared to 180 mg of Zeranol (Table I). This dose-response effect is further seen upon comparison of the combined immediate release (Ralgro) of only 18 mg with controlled release of 80 or 160 mg Zeranol, tested against immediate release alone Ralgro of 72mg (2 x 36mg).one could conclude that if you administered 33% to

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250% as much anabolic agent, you could expect as much as a 4% increase in Body Weight.

Without considering cost of drug, there would seem to be an advantage to single administration, but claiming as an immediate release formulation something not shown as effective until at the earliest 28 days after administration (table 2 shows < @ 98 mg than the 36mg Ralgro) would not seem to lead one in the art to find these effects unobvious, but not worthy of consideration over a drug combination that would provide superior efficacy.

The invention is insufficiently described to provide one in the art to discern what exactly constitutes a combined composition of an immediate release form, with immediate as tested not before 28 days from insertion, with a controlled release form as effective as shown @ the same time period –28 days.

Applicant's arguments filed 4/3/06 have been fully considered but they are not persuasive. Applicant's arguments are to the effect that immediate release is stated to constitute either zearanol alone, or Ralgro; and no one shows motivation to combine only Zearanol, providing immediate action, with a controlled release, long term dosage form in one composition for implantation. However, although examiner appreciates attorney's identifying this support, examiner finds the prior art shows one in the fattening arts would find it obvious to provide an immediate acting growth stimulant, in order to minimize feeding amount, time before shipping, feed costs for instance, while also providing a long term continual dosing form in order to continue with growth & feed

efficiency advantages & improvements, & to do so at one time, to eliminate having to do 2 implant procedures, 2 times of corralling & handling the animals, & examiner cannot determine what it is about this description that, as claimed, varies from the multiple tablets or pellets simultaneously or sequentially injected as shown in the prior art.

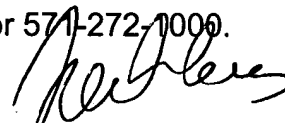
**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



NEIL LEVY  
Primary Examiner  
Art Unit 1615

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